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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,694	04/09/2004	William Alejandro Thompson	P25130	8732

7055 7590 09/15/2009

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
09/15/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/820,694	THOMPSON, WILLIAM ALEJANDRO	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-7 and 13-25* is/are pending in the application.

4a) Of the above claim(s) *1-7,13-17 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19 and 21-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment and request for RCE, both filed 07/07/2009.

Claims 1-7, 13-25 are pending.

Upon further review and consideration, claim 25 is rejoined to the prosecuted claims.

Claims 1-7, 13-17, 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/19/2007.

Claims 18, 19, 21-25 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set

forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/07/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 25 recites: "a method of treating at least one symptom as a result of transdermal delivery of an active ingredient". Recourse to the specification, nowhere applicant disclosed symptoms as a result of transdermal delivery of active agent, neither treatment of symptoms associated with transdermal delivery of active agents.

> In paragraph [0079] of the published application, applicant states: "The present invention provides a novel transdermal delivery composition comprising at least one skin permeation enhancer and at least one active ingredient permitting improved treatment and/or alleviation of pain, aches, and inflammation, and ailments associated with such symptoms. The skin permeation enhancers increase drug delivery across the skin by adsorbing to the skin and assisting in the transport of the dissolved active ingredient into the interstitial layers of the skin. When an effervescent agent is present in the composition of the present invention, the effervescent agent disperses the active ingredient to increase drug contact with the skin to further enhance drug absorption".
>
> Further, paragraph [0131] states: "The composition of the present invention, without limitation, may be used alone or in combination with a therapeutic therapy or regimen. The therapeutic

> therapy or regimen may be for treating symptoms associated with pain, aches, and/or inflammation, or may be entirely unrelated to such symptoms. For example, the present method may be incorporated as part of arthritis or allergy therapy, or in combination with cancer therapy."

In the amendment filed 09/26/2008, that added claim 25, applicant referred to paragraphs [107], [124] and [202] for support. With careful review for these paragraphs, no support has been found to the method of claim 25, especially for the limitation of "treating at least one symptom as a result of transdermal delivery of an active ingredient".

Additionally, applicant failed to describe the symptoms that may result from transdermal delivery of active ingredient. Is it local or systemic symptom; is it skin irritation, erythema, pain, headache, side effect due to the active ingredient, etc.? Are all the symptoms, either local or systemic are treatable with the claimed method using composition dissolves in water bath?

In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 19 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 19, the claim recites: "the skin permeation enhancer comprises isopropyl myristate, clarified sesame oil, and mixtures

thereof". The claim is confusing because it already recites permeation enhancer comprises both isopropyl myristate and sesame oil, and further recites their mixture. On the other hand the claim may be in improper Markush format.

With regard to claim 25, the expression "symptom as a result of transdermal delivery of an active ingredient" does not set forth the metes and bounds of the claim. Recourse to the specification does not define the expression. Further claim 25 is confusing as it recites: "wherein the transdermal delivery comprises: dissolving a composition in form of a tablet in a bath". The claim recites "device comprises", and this is followed by recitation of step method "dissolving a tablet".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 18, 22, 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramirez et al. (US 5,342,535).

Current claim 18 is directed to a method of treating and/or alleviating at least one of pain, aches, and inflammation comprising, dissolving in a bath a pharmaceutical composition for transdermal delivery comprising: at least one skin permeation enhancer; at least one effervescent agent; and at least one active ingredient or pharmaceutically

acceptable salt thereof; and immersing a body part of a human being to be treated in the bath containing the dissolved pharmaceutical composition.

Ramirez discloses effervescent tablet formulation comprising an analgesic to provide analgesic soak providing therapeutic effect when contacts the user skin (col.3, lines 36-43; col.4, lines 61-68). Example 8 at col. 7 directed to analgesic soak tablet comprising 37.5% by weight sodium bicarbonate, 36.0% by weight citric acid, 1% by weight menthol which is used as analgesic, and 2% by weight mineral oil that reads on permeation enhancer. All the amounts of the ingredients disclosed by the reference fall within the claimed ranges of claim 22. The ratio between menthol (analgesic) and mineral oil (permeation enhancer) is 1:2 which falls within the ratio of 3.0:0.5 to 0.5:3.0 required by claim 22. Example 8 further discloses that the tablet weight is 20 grams (as required by claim 23) and the tablet is added to warm water. The claimed method of treating and/or alleviating at least one of pain, ache and inflammation is implied by example 8 that is directed to "analgesic soaks" that inherently will provide analgesia. The step of immersing body part is implied by the term "soak".

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 21, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez et al. (US 5,342,535).

The teachings of Ramirez are previously discussed as set forth in this office action.

Ramirez, however, does not explicitly teach the time of soaking the body part as claimed by claim 21 and 25, or using the bath tub for immersing the body part as claimed by claim 24. The reference does not teach the method for treating symptoms as a result of transdermal delivery of an active ingredient as claimed by claim 25.

Regarding the duration for immersing a body part, those of ordinary skill in the art would have been readily optimized effective duration for application of dosages and concurrent administration regimens as determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate treatment time involving the above mentioned formulation would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation depending on individual patient, such as age, weight, sex, etc., site to be treated, and severity of condition to be treated.

Regarding claim 24, one having ordinary skill in the art would have selected the bathtub for soaking part of the body for convenience and comfort of the user. Further, Ramirez teaches adding the tablet to 50 liters of water, and this large amount of water would obviously suggest the bath tub.

With regard to claim 25, Ramirez teaches providing analgesia, and this analgesia expected to relieve any kind of pain including pain associated with transdermal drug delivery.

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Ramirez et al. (US 5,342,535), Youssefyeh (US 2001/0036489), Sharma et al. (US 5,229,130) and Buyuktimkin (US 6, 083,996).

Applicant Claims

Current claim 19 further limits claim 18 to permeation enhancer in an amount from about 1% to about 5% by weight based on the total weight of the composition; active ingredient present in an amount from about 1% by weight to about 10% by weight based on the total weight of the composition; effervescent agent present in an amount from about 30% to about 70% by weight based on the total weight of the composition; acid agent present in an amount from about 20% to about 40% by weight based on the total weight of the composition. All these amounts are disclosed by Ramirez in example 8, as set forth in this office action. Further, claim 19 recites wherein the skin permeation enhancer comprises isopropyl myristate, clarified sesame oil, and mixtures thereof; the

effervescent agent is sodium bicarbonate; the acid agent is citric acid; and the active ingredient is ibuprofen; wherein the composition is a tablet; and wherein the method is performed at least twice during a 24 hour period.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Ramirez teaches effervescent tablet formulation comprising an analgesic to provide analgesic soak providing therapeutic effect when contacts the user skin (col.3, lines 36-43; col.4, lines 61-68). Example 8 at col. 7 directed to analgesic soak tablet comprising 37.5% by weight sodium bicarbonate, 36.0% by weight citric acid, 1% by weight analgesic menthol, and 2% by weight mineral oil that reads on permeation enhancer. Example 8 further teaches that the tablet weight is 20 grams (as required by claim 23) and the tablet is added to warm water. The claimed method of treating and/or alleviating at least one of pain, ache and inflammation is implied by example 8 that is directed to "analgesic soaks" that will provide analgesia. The step of immersing body part is implied by the term "soak".

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Ramirez teaches analgesic soaks comprising menthol as analgesic and mineral oil that acts as permeation enhancer, however, the reference does not explicitly

teach ibuprofen as analgesic agent, or the specific permeation enhancers as claimed by claim 19.

Youssefyeh teaches treating rheumatoid arthritis and osteo-arthritis pain using bathing composition comprising anti-inflammatory agent including ibuprofen and safflower oil for at least once a day (paragraphs 0094-0101; 0140, 0141). The composition may comprise sodium bicarbonate and citric acid (paragraph 0126).

Sharma teaches method for increasing the flux of drugs across the skin using topical composition comprising vegetable oils in combination with other enhancers. Preferred vegetable oils include sesame oil. Combination of enhancers forms from 5-25% of the topical composition. Drugs include analgesics. See abstract; col.3, lines 65-68; col.4, lines 13-16; col.5, lines 3-5, 40-45; claim 1.

Buyuktimkin teaches topical formulation for NSAID delivery for management of pain comprising drug and permeation enhancer including isopropyl myristate (abstract; co1.1, lines 10-14; col.2, lines 1-5; col.4, lines 1-60; col.6, lines 47-49, examples). Example 27 at co1.17 shows the composition comprising 5% ibuprofen and 5% isopropyl myristate.

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide tablet to be dissolved in water comprising analgesic soak comprising effervescent agent, acid, analgesic and mineral oil as taught by

Ramirez, and replace the analgesic with ibuprofen taught by Youssefyeh and apply the composition at least once a day. One would have been motivated to do so because Ramirez desired to provide analgesia by soaking/bathing part of the body afflicted with pain in composition comprising analgesic and Youssefyeh teaches that pain can be treated by composition comprising ibuprofen, safflower oil, bicarbonate and citric acid added to bathwater that used at least once a day. One would reasonably expect treating pain by bathing or soaking part of the body suffering from pain in bath comprising effervescent agent, acid, ibuprofen and oils wherein the pain is relieved effectively.

Additionally, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide analgesic soak tablet to be dissolved in water comprising effervescent agent, acid, ibuprofen and oil as taught by Ramirez combined with Youssefyeh, and further replace the oils with sesame oils combined with other enhancer taught by Sharma. One would have been motivated to do so because Sharma teaches that sesame oil enhances the flux of drugs through the skin and can be used combined with other permeation enhancers. One would reasonably expect treating pain by bathing or soaking part of the body suffering from pain in bath comprising effervescent agent, acid, ibuprofen and sesame oil and other permeation enhancer wherein the flux of ibuprofen to the skin is enhanced.

Further more, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat pain by bathing or soaking part of the body suffering from pain in bath comprising effervescent agent, acid, ibuprofen, sesame oil and other permeation enhancer as taught by the combined teachings of Ramirez, Youssefyeh and

Sharma, and replace the permeation enhancer with isopropyl myristate taught by Buyuktimkin. One would have been motivated to do so because Buyuktimkin teaches that isopropyl myristate is preferred enhancer for ibuprofen for topical delivery and pain management. One would reasonably expect treating pain by bathing or soaking part of the body suffering from pain in bath comprising effervescent agent, acid, ibuprofen, sesame oil and isopropyl myristate wherein the flux of ibuprofen to the skin is enhanced to achieve the desired analgesic effect.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claim Objections

12. Claim 25 is objected to because of the following informalities: the claim is missing a period at the end of the claim. Appropriate correction is required.

Response to Arguments

13. Applicant's arguments with respect to claims 18, 19, 21-25 have been considered but are moot in view of the new ground(s) of rejection.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-

0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611